

### **REMARKS**

Claims 1-13, 23-36, 53-66, 69-70 and 72 are pending in the current application.

### **ELECTION/RESTRICTION**

A requirement for restriction has been made under 37 C.F.R. 1.499 between the inventions of Groups:

- I. Claims 1-5, drawn to an immunogenic composition comprising a polypeptide and a pharmaceutically acceptable excipient.
- II. Claims 6-8, drawn to an immunogenic composition comprising a polynucleotide.
- III. Claims 9-10, drawn to an immunogenic composition comprising a polynucleotide encoding a polypeptide.
- IV. Claims 11-13, 23-36, 53-66 and 72, drawn to an immunogenic composition comprising at least or exactly two, three, four, five, six, seven, eight, nine or ten different Bordetella antigens.
- V. Claims 69-70, drawn to a method for treating or preventing Bordetella infection.

Applicants elect Group IV with traverse. Applicants respectfully submit that Wang et al. (WO200277183) published without a sequence listing; the sequence listing was only provided on a CD-ROM (see page 1, lines 2-7). Therefore, the Examiner has not established that Groups I-V lack the same or corresponding technical feature.

### **Election of Species Requirement to Group IV**

For Group IV, Applicants were further required to elect species from Group A, Group B4 and Group B5, Group C and Group D.

**Group A Bordetella antigen species:**

Applicants were required to elect a species of antigens from at least (1) two antigens, (2) three antigens, (3) four antigens, (4) five antigens, (5) six antigens, (6) seven antigens, (7) eight antigens, (8) nine antigens, and (9) ten antigens.

**Applicants elect at least three antigens.**

**Group B: Election of Species and Election of SEQ ID NO(s):**

Applicants were further required to elect a combination of polypeptides or proteins which equal the number of antigens selected in Group A from:

- (1) Bordetella autotransporter protein selected from the group consisting of a polypeptide sharing at least 70% identity with SEQ ID 34;
- (2) Bordetella iron acquisition protein-selected from the group consisting of a polypeptide sharing at least 70% identity with SEQ ID NOs: from the list below:
  - (a) SEQ ID NOs: 2, 4, 6, 8, 10, 12, 14, 16, 18, 20, 22, 24, 26, or 28;
  - or
  - (b) an antigenic fragment thereof of SEQ ID NOs: 2, 4, 6, 8, 10, 12, 14, 16, 18, 20, 22, 24, 26, or 28;
- (3) Bordetella lipoprotein selected from the group consisting of a polypeptide sharing at least 70% identity with SEQ ID NOs: from the list below:
  - (a) SEQ ID NOs: 56, 58, 60, 62, 64, 66, 68, 70, 72, 74, 76, 78, 80, 82, 84, 86, 88, 90, 92, 94, 96, or 98;
  - or
  - (b) an antigenic fragment thereof of SEQ ID NOs: 56, 58, 60, 62, 64, 66, 68, 70, 72, 74, 76, 78, 80, 82, 84, 86, 88, 90, 92, 94, 96, or 98;
- (4) Bordetella adhesin/Bordetella adhesin antigenic fragments thereof: (a) FHA, (b) fimbriae 2 and/or 3, (d) pertactin, (e) BrkA, (f) antigenic fragment of FHA, (g)

antigenic fragment of fimbriae 2 and/or 3, (h) antigenic fragment of pertactin, and (i) antigenic fragment of BrkA; and

(5) Bordetella toxin/invasin or antigens or antigenic fragments thereof involved in toxin/invasin secretion: (a) pertussis toxin, (b) adenylate cyclase, (c) dermonecrotic toxin (Dnt), (d) Type III ss, (e) lipopolysaccharide, (f) antigenic fragment of pertussis toxin, (g) antigenic fragment of adenylate cyclase, (h) antigenic fragment of dermonecrotic toxin (Dnt), (i) antigenic fragment of Type III ss, (j) antigenic fragment of lipopolysaccharide,

wherein the Bordetella antigens in the immunogenic composition do not consist of any combination of 2, 3, 4 or all 5 of pertactin, fimbriae 2, fimbriae 3, FHA and pertussis toxin.

**Applicants elect groups (1), (4) and (5) from Group B:**

(1) Bordetella autotransporter protein selected from the group consisting of a polypeptide sharing at least 70% identity with SEQ ID 34;

(4) Bordetella adhesin/Bordetella adhesin fragment thereof (a) FHA, (b) fimbriae 2 and/or 3, (d) pertactin, (e) BrkA, (f) antigenic fragment of FHA, (g) antigenic fragment of fimbriae 2 and/or 3, (h) antigenic fragment of pertactin, and (i) antigenic fragment of BrkA; and

(5) Bordetella toxin/invasin or antigens or antigenic fragment thereof involved in toxin/invasion secretion (a) pertussis toxin, (b) adenylate cyclase, (c) dermonecrotic toxin (Dnt), (d) Type III ss, (e) lipopolysaccharide, (f) antigenic fragment of pertussis toxin, (g) antigenic fragment of adenylate cyclase, (h) antigenic fragment of dermonecrotic toxin (Dnt), (i) antigenic fragment of Type III ss, and (j) antigenic fragment of lipopolysaccharide.

Applicants note that Group (1) should also include antigenic fragments of SEQ ID NO: 34.

**Further Group B elections:**

**Group B4 Election:**

If Applicants elected a combination comprising Bordetella adhesin/Bordetella adhesin fragments thereof, from Group B4, a further election was required from: (a) FHA, (b) fimbriae 2 and/or 3, (d) pertactin (c) BrkA, (f) antigenic fragment of FHA, (g) antigenic fragment of fimbriae 2 and/or 3, (h) antigenic fragment of pertactin; and (i) antigenic fragment of BrkA.

**Applicants elect (a) FHA from Group B4.**

**Group B5:**

If Applicants elected a combination comprising Bordetella toxin/invasin or antigens or antigenic fragments thereof, from Group B5, a further election was required from: (a) pertussis toxin, (b) adenylate cyclase, (c) dermonecrotic toxin (Dnt), (d) Type III ss, (e) lipopolysaccharide, (f) antigenic fragment of pertussis toxin, (g) antigenic fragment of adenylate cyclase, (h) antigenic fragment of dermonecrotic toxin (Dnt), (i) antigenic fragment of Type III ss, and (j) antigenic fragment of lipopolysaccharide.

**Applicants elect (a) pertussis toxin from Group B5.**

**Group C Election:**

Applicants were further required to elect a Phase species from: (1) Bvg+ early phase; (2) Bvg+ late phase; (3) Bvgi phase; and (4) Bvg- phase.

**Applicants elect (1) Bvg+ early phase.**

**Group D Election:**

Applicants were further required to elect a species of the generic invention for Group IV from:

1. Toxoid
2. PRP capsular oligosaccharide or polysaccharide from Haemophilus Influenzae B Polysaccharide;

3. Hepatitis B surface antigen (HbsAg);
4. Inactivated Polio Vaccine (IPV);
5. N. meningitidis protein;
6. Men A, C, W, or Y capsular polysaccharides or oligosaccharides;
7. Capsular polysaccharides or oligosaccharides from S. pneumoniae;
8. Killed Attenuated Hepatitis A virus.

Applicants elect **(3) Hepatitis B surface antigen (HbsAg)**.

Applicants elect the species for purposes of initial examination on the merits. In the event that a generic claim is found allowable, Applicants understand that additional species which depend from and otherwise include all the limitations of the generic claims will be considered as provided by 37 CFR § 1.141.

Claims 11-13, 23-36, 53-66 and 72 read on the elected invention.

Applicants also note that the subject matter of Groups IV and V are related to each other as product and a process of using the product, respectively. When product claims (for example, one or more of Claims 11-13, 23-36, 53-66 and/or 72) are found to be allowable, Applicants respectfully request rejoinder of process claims that are dependent or otherwise include all the limitations of the allowed product claims as required by MPEP § 821.04(b).

Applicants expressly reserve the right to prosecute the subject matter in the non-elected claims, originally filed claims, or any other claims supported by the specification in one or more continuing applications.

### **CONCLUSION**

Applicants elect **Group IV with traverse** and further elect the following species:

**Group A: at least three antigens.**

**Group B: Groups (1), (4) and (5).**

**Group B4: (a) FHA.**

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**Group B5: (a) pertussis toxin.**

**Group C: (1) Bvg+ early phase.**

**Group D: (3) Hepatitis B surface antigen (HbsAg).**

Should any outstanding issues remain, the Examiner is encouraged to contact Applicants' undersigned representative.

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